K013647

SYBRON DENTAL SPECIALTIES

JAN 1 6 2002

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
(714) 516-7488 - Facsimile
Colleen Boswell - Contact Person

Date Summary Prepared: November 2001

Device Name:

- Trade Name – *Revolution Formula 2*
- Common Name – Light-Curable Dental Restorative Material
- Classification Name – Tooth Shade Resin Material, per 21 CFR § 872.3690

Devices for Which Substantial Equivalence is Claimed:

- Kerr Corporation, *Prodigy 3*

Device Description:

The device is a light cured, hybrid resin dental restorative which incorporates BIS-GMA chemistry along with a proprietary glass filler (approximately 60%) to yield a flowable non-slumping restorative material. *Revolution Formula 2* combination of flowability and direct application system simplifies material placement and minimizes finishing to result in a consistently superior restoration.

Intended Use of the Device:

The intended use of *Revolution Formula 2* is for the restoration of Class III, Class IV, and Class V cavities, repair of enamel defects, repair of porcelain restorations, minor occlusal build-ups in non-stress bearing areas, pit and fissure sealant, cement for ceramic/composite veneers, incisal abrasions, and core build-ups.

Substantial Equivalence:

Revolution Formula 2 is substantially equivalent to other legally marketed devices in the United States. The dental composite restorative material marketed by Kerr Dental Materials Center functions in a manner similar to and is intended for the same use as the product manufactured by Kerr Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 6 2002

Ms. Colleen Boswell
Director, Corporation Compliance
Sybron Dental Specialties, Inc.
1717 West Collins Avenue
Orange, California 92867

Re: K013647
Trade/Device Name: Revolution Formula 2
Regulation Number: 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: November 02, 2001
Received: November 05, 2001

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section I

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Kerr Dental Material Center

510(k) Number (if known): K013647

Device Name: Revolution Formula 2

Indications For Use:

Revolution Formula 2 is a flowable, light cure hybrid resin restorative designed to be used as a filling material for Class III, Class IV, and Class V restorations. Additional functions include: repair of enamel defects, repair of porcelain restorations, minor occlusal build-ups in non-stress bearing areas, pit and fissure sealant, cement for ceramic/composite veneers, incisal abrasions, and core build-ups.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013647

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)